7. 510(k) SUMMARY

DEC 2 0 2010

General Information

Classification	Class II
Trade Name	UltraSightHD™ Digital Colposcopy System with ImageSense™ Technology
Common Name:	Colposcope (21 CFR 884.1630),
Manufacturer	STI Medical Systems, LLC 99-193 Aiea Heights Drive, Suite 139 Aiea, HI USA 96701
Contact	Rolf Wolters Senior Vice President Telephone Number: (808) 540-4728

Date Summary Prepared: December 12, 2010

Intended Use / Indications for use:

UltraSightHD™ with ImageSense™ is a digital colposcope designed to image the cervix and lower genital tract under illumination and magnification. Colposcopy is indicated for women with an abnormal Pap smear in order to affirm normality or detect abnormal appearances consistent with neoplasia, often with directed biopsy.

OpacityViewer™ is an ImageSense™ digital filter for displaying areas of acetowhitening. It is a tool that should NOT be used as a substitute for a thorough colposcopic evaluation.

Predicate Device

The predicate device is the Cervical MD Model C10, STI Medical Systems, K072691, January 31, 2008. The proposed device differs from the predicate with respect to the addition of new imaging features referred to as ImageSense™.

Device Description

The UltraSight HD™ Digital Colposcopy System with ImageSense™ Technology is a digital colposcope designed to image the cervix and lower genital tract under illumination and magnification.

ImageSense™ is an image processing suite available for the UltraSightHD™ digital colposcope. The ImageSense™ suite consists of two different modules: UltraGreen™ filter and Acetowhite OpacityViewer™.

The UltraGreen™ filter provides the user with greater contrast than an unprocessed image. UltraGreen™ is displayed as a regular full color image, and is available to be used on any still-frame image displayed in the *Review Hi-Res Imagery, View ImageSense Results,* and *Annotate Image* modes.

The Acetowhite OpacityViewer™ compares two images, one taken prior to the application of Acetic Acid and an additional image taken 60 seconds after the application of Acetic Acid, otherwise known as the pre- and post- Acetic Acid images. The Acetowhite OpacityViewer™ then generates a

difference map that shows the extent of white difference between the two images, which is indicated by a gradient color scale ranging from blue (no measurable difference between the images), through white (some difference) and yellow (moderate difference), to red (large difference). Red, on the difference map, indicates only the greatest color difference between the images.

(Note: The UltraSightHD™ with ImageSense™ has not been shown to identify areas of cervical neoplasia. Therefore, this system should not be used to omit a biopsy selected on the basis of colposcopic examination.)

The illumination and optical design of the device allow the user to capture high resolution digital images. The optical subsystem is augmented by integrated image quality assessment algorithms, ensuring that focused and balanced-contrast images are acquired. Two liquid crystal displays (LCDs) provide video display and user interface information. The software includes functionality for annotating, filtering and storing the images on external PACS servers via the DICOM protocol.

Materials

The materials in the UltraSightHD™ Digital Colposcope are suitable for their intended use and have been used in previously cleared products. The device is not patient contacting and therefore no biocompatibility testing was required.

Testing

Appropriate risk analysis-driven product testing was conducted to evaluate conformance to product specification and substantial equivalence to the predicate device.

Testing included assessments of the following:

- Electrical Safety
- Electromagnetic Compatibility
- Optical Radiation
- Resolution
- Distortion
- Illumination Variance
- Image Registration
- Color Difference Map Range
- Mechanical Subsystem
    - Ease of movement
    - Orientation motion of the optic system (pitch/yaw)
    - Settling time of motion caused by release of aiming handle
    - Affect of internal vibration on image
    - Imaging system height adjustment

Clinical Studies

The only clinical studies conducted were run to validate image registration.

No clinical studies were conducted to demonstrate improved clinical performance using the new OpacityViewer digital filter.

Test results indicate that the device meets the performance specifications.

Summary of Substantial Equivalence

The UltraSightHD™ Digital Colposcopy System with ImageSense™ Technology is equivalent to the Cervical MD Model C10 predicate device. The indications for use, basic overall design and function, product performance, and materials used are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Rolf Walters, Ph.D.
Senior Vice President
STI Medical Systems, LLC
733 Bishop Street, Suite 3100
HONOLULU HAWAII 96813

DEC 20 2010

Re: K090324
Trade/Device Name: UltraSightHD™ Digital Colposcopy System with ImageSense™ Technology
Regulation Number: 21 CFR §884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: October 23, 2009
Received: October 29, 2009

Dear Dr. Walters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC 20 2010

510(k) Number (if known): K090324

Device Name: UltraSightHD™ Digital Colposcopy System with ImageSense™ Technology

Indications For Use:

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Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K090324